

Message Text

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21

ORIGIN HEW-06

INFO OCT-01 ARA-10 EA-10 ISO-00 OES-05 /032 R

66610

DRAFTED BY: DHEW/FDA:JRWEINROTH, MD

APPROVED BY: OES/SCI/BMP:MBAUBIEN

DHEW/OIH:MACODDING

ARA/CEN:JGSULLIVAN (INFO)

EA/K:RMAYHEW (INFO)

----- 100386

R 252153Z MAR 75

FM SECSTATE WASHDC

TO AMEMBASSY SAN JOSE

AMEMBASSY SEOUL

UNCLAS STATE 067441

E.O. 11652: N/A

TAGS: OGEN, ETRD, TBIO, CS, KS

SUBJ: FDA ADVISORY - LEAKING DRUG CONTAINERS

FDA ADVISES THAT HYPAAQUE MEGLUMINE 60 PERCENT BRAND OF MEGLUMINE DIATRIZOATE, U.S.P. STERILE AQUEOUS INJECTION MANUFACTURED BY WINTHROP LABORATORIES, DIVISION OF STERLING DRUG, INC., NEW YORK, NY 10016 PACKAGED AS 25/30 ML. VIALS PER SHELF CARTON, LOT NUMBERS 216KH, 270LH, 290LH, ARE BEING RECALLED FROM THE MARKET.

THE REASON FOR THE RECALL IS THAT THE FIRM HAS FOUND SOME VIALS TO LEAK AS A RESULT OF THE VIAL NECK BEING BROKEN UNDER THE ALUMINUM CRIMP SEAL.

FOREIGN CONSIGNEES AS FOLLOWS:

A. CAJA COSTARRICENSE DE SEGURO SOCIAL, APARTADO 10105 SAN JOSE, COSTA RICA - RECEIVED 70 BOXES.

B.G. WANG AND CO. LTD., SEOUL, KOREA - RECEIVED 112 BOXES.

POSTS ARE REQUESTED TO CONTACT CONSIGNEES TO DETERMINE IF THEY
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HAVE RECEIVED LETTERS FROM FIRM CONCERNING THIS RECALL. THEY

MAY ALSO WISH TO ADVISE HOST COUNTRY DRUG CONTROL AUTHORITIES.
KISSINGER

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NNN

Message Attributes

Automatic Decaptioning: X
Capture Date: 01 JAN 1994
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: DRUGS, RECALLS
Control Number: n/a
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Draft Date: 25 MAR 1975
Decaption Date: 01 JAN 1960
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Authority: n/a
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01 JAN 1960
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
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Review Comment: n/a
Review Content Flags:
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Review Exemptions: n/a
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Margaret P. Grafeld
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05 JUL 2006

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TAGS: OGEN, ETRD, TBIO, CS, KS
To: SAN JOSE SEOUL
Type: TE
Markings: Margaret P. Grafeld Declassified/Released US Department of State EO Systematic Review 05 JUL 2006